1083001

OCT 2 2 2008

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned	510(k)) number is:	

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888 Fax: +86 755 2658 2680

Contact Person:

Li Dongling Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: August 31, 2008

2. Device Name: M5 Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

The subject device is substantially equivalent in its technologies and functionality to the original M5 Diagnostic Ultrasound System that is already cleared under premarket notification number K080640, and the other predicate devices are listed below: Mindray DC-6 (K072164), GE logiq 9 (K061129), GE Logiq E (K072797), Mindray DP-6600 (K060949), Philips IU22 (K042540).

4. Device Description:

The M5 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transvaginal, intraoperative (abdominal, thoracic, and vascular etc.), pediatric, neonatal cephalic, musculoskeletal (general and superficial).

6. Safety Considerations:

The M5 Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 1997. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the M5 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

OCT 2 2 2008

Shenzhen Mindray Bio- Medical Electronics Co., Ltd. % Mr. Robert Mosenkis
President
CITECH Medical Device Testing and Consulting
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K083001

Trade/Device Name: M5 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: October 7, 2008 Received: October 8, 2008

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M5 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5s 6C2s 6CV1s

7L4s, 7L6s, 10L4s

<u>6LE7s</u>

6LB7s

3C1s 2P2s 7L5s 7LT4s

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (240) 276-3666.

Singerely yours

oyce M. Whang, Ph.D.

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System	×	Transducer		
Model:		M 5		
510(k) Number(s)	•	KOE	3001	

				Mode of Operation												
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)						
Ophthalmic																
Fetal		P	P	Ъ		P	P		P	Note 1, 2, 3, 4						
Abdominal		P	P	Р	N	P	P		P	Note 1, 2, 3, 4						
Intraoperative (specify)*		Ν	N	N		N	N		N	Note 2, 3, 4						
Intraoperative Neurological																
Pediatric		P	P	Р	N	P	Р		P	Note 1, 2, 3, 4						
Small organ(specify)**		P	P	P		P	P		Р	Note 2, 3, 4						
Neonatal Cephalic		P	P	P	N	P	P		P	Note 1,2, 3, 4						
Adult Cephalic		P	P	P	N	P	P		P	Note 1,2, 3						
Cardiac		P	P	P	N	P	P		P	Note1,2, 3						
Transesophageal							-			· · · · · · · · · · · · · · · · · · ·						
Transrectal		P	P	P		P	P		P P	Note 2, 3, 4						
Transvaginal		P	P	P		P	P		P	Note 2, 3						
Transurethral																
Intravascular																
Peripheral Vascular		P	P	P	[P	Р		P	Note 1, 2, 3, 4						
Laparoscopic						_										
Musculo-skeletal Conventional		P	P	Р		P	P		P	Note 2, 3, 4						
Musculo-skeletal Superficial		Р	P	P		P	P		P	Note 2, 3, 4						
Other (specify)***		P	P	P		P	P		Р	Note1, 2, 3, 4						

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B	3.
*Intraoperative includes abdominal, thoracic, and vascular etc.	
**Small organ-breast, thyroid, testes, etc.	
***Other use includes Urology/Prostate.	
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.	
Note 2: Smart3D	
Note 3: iScape	
Note 4: iBeam	

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_____

System		_		I rans	ducer	×	_			
Model:		30	25s							
510(k) Number(s)				Pine T	•					
							•			
						Mo	de of Opera	ition		
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	1							- 5 0		
Fetal		P	P	P		P	P		P	Note 1, 2, 3
Abdominal		P	P	Р		P	P		P	Note 1, 2, 3
Intraoperative (specify)*					i					1,010 1, 2, 3
Intraoperative Neurological		1								
Pediatric		P	P	P		P	P		Р	Note 1, 2, 3
Small organ(specify)**						,				11010 1, 2, 3
Neonatal Cephalic										
Adult Cephalic	1"-			 						
Cardiac		_								
Transesophageal				1	<u> </u>					
Transrectal	· · · -									
Transvaginal		1			-					·
Transurethral				1						
Intravascular				 				<u> </u>	-	
Peripheral Vascular		N	N	N		N	N	-	N	Note 1, 2, 3
Laparoscopic	Ţ -			<u> </u>						11010 1, 2, 3
Musculo-skeletal Conventional	i			1						
Musculo-skeletal Superficial	i -			t						
Other (specify)***	Ì	N	N	N		N	N		N	Note 1, 2, 3
N=new indication; P=previously	cleare	d by F	DA; I	=adde	ed under	Appendix I	<u></u>	<u> </u>	<u> </u>	1,010 1, 2, 3
Additional comments:Combined								+ B. Power	+ PW +B.	
*Intraoperative include										
**Small organ-breast										· · · · · · · · · · · · · · · · · · ·
***Other use include:	s Urole	ogy.					· · · · · · · · · · · · · · · · · · ·	- · · · · · ·		·
Note 1: Tissue Harmo	nic In	naging	The	feature	does no	t use contra	ist agents.	_		
Note 2: Smart3D										
Note 3: iScape							- · · · · · · · · · · · · · · · · · · ·			
Note 4: iBeam										
	,	**								
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

System				Trans	ducer	×				
Model:		6C	2s							
510(k) Number(s)										
						·				
						Mo	de of Opera	tion .		
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal				1						
Abdominal		P	P	P		P	P		P	Note 2, 3
Intraoperative (specify)*	1									<u></u>
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Р	Note 2, 3
Small organ(specify)**										
Neonatal Cephalic	·	P	P	P		Р	P		Р	Note 2, 3
Adult Cephalic		P	P	P		P	P		P	Note 2, 3
Cardiac	Ī	P	P	P		P	P		Р	Note 2, 3
Transesophageal										
Transrectal	1									
Transvagina!										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic								1		
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										, ,, -
Other (specify)***		N	N	N		N	N		N	Note 2, 3
N=new indication; P=previously	cleare	d by F	DA;	E=add	ed under	Appendix	E			
Additional comments:Combined	mode	s: B+N	۸, PW	/+B, C	olor + B	, Power + I	3, PW +Color	r+ B, Powe	r + PW +B.	
*Intraoperative include	des abo	domin	ai, the	racic,	and vaso	ular etc.				
**Small organ-breast	, thyre	oid, tes	tes, e	tc.						
***Other use include	s Urol	ogy.							•	
Note 1: Tissue Harmo	onic Ir	naging	. The	featu	e does n	ot use contr	ast agents.			
Note 2: Smart3D										
Note 3: iScape						•		•		
Note 4: iBeam		-							-	
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number

System		-		I rans	sducer	_×							
Model:		6C	Vis										
510(k) Number(s)													
							•						
		Mode of Operation											
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify			
Ophthalmic							<u> </u>	illaging.					
Fetal	_	P	P	P		P	P		P	Note 2, 3			
Abdominal			 	†			 			Note 2, 3			
Intraoperative (specify)*		l		1									
Intraoperative Neurological				 	_		-						
Pediatric			<u> </u>	1	ļ —								
Small organ(specify)**				1		· · · · · ·							
Neonatal Cephalic							 		_				
Adult Cephalic			-			-	 	,					
Cardiac		<u> </u>		1					-				
Transesophageal		<u> </u>	1 -	 				-					
Transrectal		P	P	P		P	P		P	Note 2, 3			
Transvaginal		P	P	P		P -	P		P	Note 2, 3			
Transurethral				 -			<u> </u>			14016 2, 3			
Intravascular				 			 						
Peripheral Vascular			_		-		-						
Laparoscopic				 									
Musculo-skeletal Conventional				 									
Musculo-skeletal Superficial			<u> </u>	 						-			
Other (specify)***		P	P	P		P	P -		P	Note 2, 3			
N=new indication; P=previously	cleare	d by F	DA: F	=adde	ed under		_		<u> </u>	Note 2, 3			
Additional comments:Combined	modes	: B+N	1. PW	+8. C	olor + B.	Power + B	PW +Color	+ B Pawer	+ DW +D				
*Intraoperative includ	es abd	omina	ıl. tho	racic. a	and vasc	ılar etc	,1 17 (COIOI	, D, TOWE	T T W TD.				
**Small organ-breast,													
***Other use includes					-								
Note 1: Tissue Harmo	_		. The	feature	does no	t use contra	est agents						
Note 2: Smart3D							in agonts.						
Note 3: iScape													
Note 4: iBeam					-								
(PLEASE DO N	OT W	RITF	BELC)W TF	IIS LINI	E-CONTIN	LIE ON ANO	THED DAY	GE IE MEEDI	ED)			
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number_

System	Transducer X										
Model:	7L	4s, 7L	6s, 10	L4s			•				
510(k) Number(s)		•	1								
						Mo	de of Opera	ition			
Clinical Application	А	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic								***************************************	-		
Fetal											
Abdominal		N	N	N		N	N		N	Note 2, 3, 4	
Intraoperative (specify)*									· · · ·	11010 2, 3, 4	
Intraoperative Neurological				i							
Pediatric		N	N	N	_	N	N		N	Note 2, 3, 4	
Small organ(specify)**	<u> </u>	P	P	P		P	P	·	P	Note 2, 3, 4	
Neonatal Cephalic	1	P	P	Р		P	P		P	Note 2, 3, 4	
Adult Cephalic	T			1						11010 2, 3, 4	
Cardiac						-				1	
Transesophageal											
Transrectal				1							
Transvaginal							1				
Transurethral											
Intravascular										<u> </u>	
Peripheral Vascular		P	Р	P		P	Р	_	P	Note 2, 3, 4	
Laparoscopic				1		-					
Musculo-skeletal Conventional		Р	P	P		Р	P		Р	Note 2, 3, 4	
Musculo-skeletal Superficial		P	P	P		Р	P		P	Note 2, 3, 4	
Other (specify)***											
N=new indication; P=previously	cleare	d by F	DA; I	E≕add	ed under	Appendix	E	<u> </u>	<u> </u>		
Additional comments:Combined								+ B, Power	+ PW +B,		
*Intraoperative include						·					
**Small organ-breast	, thyro	id, tes	tes, et	c.		·· <u>-</u> -					
***Other use include	s Urolo	gy.									
Note 1: Tissue Harmo	onic In	aging	The	featur	does no	t use contr	ast agents.			, .	
Note 2: Smart3D		•									
Note 3: iScape			•								
Note 4: iBeam											
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							ice Evalua			<u>,</u>	

Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

System				Trans	ducer	×	<u>.</u>			
Model:		6L1	E7s		_					
510(k) Number(s)										
							•			
						Mo	de of Opera	ition		
Clinical Application	Α	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				1						
Fetal		P	Р	P		P	P		P	Note 2, 3, 4
Abdominal				\Box						
Intraoperative (specify)*										
Intraoperative Neurological							<u> </u>			
Pediatric					Î					•
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac			<u> </u>							
Transesophageal					i		1			
Transrectal		P	P	P		P	P		P	Note 2, 3, 4
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular]									
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial			<u> </u>	T						-
Other (specify)***		P	P	P		Р	P		P	Note2, 3, 4
N=new indication; P=previously	cleare	d by I	DA;	E=add	led unde	Appendix	Е			
Additional comments:Combined	mode	s: B+l	M, PV	√+B, C	Color + E	, Power + 1	B, PW +Colo	r+ B, Powe	r + PW +B.	
*Intraoperative include	des abo	lomin	al, the	эгасіс,	and vas	cular etc.				
**Small organ-breast	t, thyro	id, tes	ites, e	tc.						
***Other use include	s Urol	ogy.								
Note 1: Tissue Harme	onic In	naging	z. The	featur	re does n	ot use conti	rast agents.			_
Note 2: Smart3D										
Note 3: iScape										
Note 4: iBeam										
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Prescription USE (Per 21 CFR 80 .109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

System				Trans	ducer	×	_			
Model:		6L1	B7s							
510(k) Number(s)			1				_			
				_		Mo	de of Opera	ition		
Clinical Application	Α	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal				 						
Intraoperative (specify)*				İ			1			
Intraoperative Neurological										
Pediatric										
Small organ(specify)**				!	1			-		
Neonatal Cephalic										
Adult Cephalic									T	7.7.
Cardiac								<u> </u>		
Transesophageal										
Transrectat		P	P	P		P	P		P	Note 2,3,4
Transvaginal										
Transurethral						1				
Intravascular										
Peripheral Vascular								1		
Laparoscopic										
Musculo-skeletal Conventional		Ĺ				I				
Musculo-skeletal Superficial				"						
Other (specify)***		P	P	P		P	P		P	Note 2,3,4
N=new indication; P=previously	cleare	d by F	DΑ;	E=add	ed under	Appendix	E			
Additional comments:Combined	mode	s: B+N	M, PW	/+B, C	olor + B	, Power + I	3, PW +Color	r+ B, Powe	r + PW +B.	
*Intraoperative include	ies abo	iomin	al, tho	гасіс,	and vaso	ular etc.			· · · · · ·	
**Small organ-breast	, thyro	id, tes	tes, e	tc.						
***Other use include	s Urol	ogy/P	rostate	3.						
Note 1: Tissue Harmo	onic In	naging	z. The	featur	e does n	ot use contr	ast agents.			
Note 2: Smart3D										
Note 3: iScape										<u> </u>
Note 4: iBeam										
				•						
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

System		_		Tran	sducer	×					
Model:		3C	Cls								
510(k) Number(s)											
							· 			-	
						Mo	de of Operation				
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic				 	 		,				
Fetal										 -	
Abdominal		N	N	N		N	N		N	Note 1, 2, 3	
Intraoperative (specify)*											
Intraoperative Neurological							-				
Pediatric		N	N	N		N	N		N	Note 1, 2, 3	
Small organ(specify)**											
Neonatal Cephalic										******	
Adult Cephalic											
Cardiac		И	N	N		N	N		N	Note 1, 2, 3	
Transesophageal											
Transrectal											
Transvaginal			-								
Transurethral		-								 	
Intravascular											
Peripheral Vascular		I									
Laparoscopic		T									
Musculo-skeletal Conventional				1		-					
Musculo-skeletal Superficial				1							
Other (specify)***											
N=new indication; P=previously	/ clear	ed by	FDA	; E=ac	ided und	er Appendi	хE	<u> </u>			
Additional comments:Combined								lor+B, Po	wer + PW +E	3.	
*Intraoperative inclu											
**Small organ-breas	_									·	
***Other use include	s Uro	logy.					· • • • • • • • • • • • • • • • • • • •			,	
Note 1: Tissue Harm	onic I	magir	ıg. Th	e feat	ure does	not use cor	ntràst agents.			-,	
Note 2: Smart3D							•				
Note 3: iScape								_			
Note 4: iBeam							<u>-</u>		*···		
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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

System				Trans	ducer	×	_			
Model:		2₽	2s							
510(k) Number(s)					· 		_			
				-		Mo	de of Opera	ition		
Clinical Application	٨	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Ophthalmic				<u> </u>						
Fetal										
Abdominal		N	N	N	N	N	N		N	Note 1, 2
Intraoperative (specify)*				1						
Intraoperative Neurological									1	
Pediatric		И	N	N	N	N	N		N	Note 1, 2
Small organ(specify)**				1	1					
Neonatal Cephalic		N	N	N	N	N	N		N	Note 1, 2
Adult Cephalic		N	N	N	N	N	N		N	Note 1, 2
Cardiac		N	N	N	N	N	N		N	Note 1, 2
Transesophageal							1		1	
Transrectal										
Transvaginal									<u> </u>	
Transurethral				T						
Intravascular								1		
Peripheral Vascular										1
Laparoscopic				1		Ī			· ·	
Musculo-skeletal Conventional	1							Ì		
Musculo-skeletal Superficial										
Other (specify)***				1						
N=new indication; P=previously	y clear	ed by	FDA	; E=a	ded und	ler Append	lix E			
Additional comments:Combined	d mod	es: B-	-M, P	W+B,	Color+	B, Power	+ B, PW +Co	olor+ B, Po	wer + PW +	В.
*Intraoperative inclu	ides al	odomi	nal, tl	horaci	c, and va	ascular etc.				
**Small organ-breas										
***Other use include	es Urc	ology.								
Note 1: Tissue Harm	ionic l	magi	ıg. Ti	ne feat	ure does	not use co	ntrast agents			
Note 2: Smart3D										
Note 3: iScape		-								
Note 4: iBeam										***
									=	
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Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices

System				Tran	sducer	×				
Model:		71	-5s				-			
510(k) Number(s)					•					
							-			
						Mo	de of Opera	ation	· · · · · ·	
Clinical Application	A	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		 	-	 	<u> </u>			imaging		·
Fetal		1	<u> </u>				-			
Abdominal	t —	N	N	N	ļ <u>.</u>	N	N		N	Note 2 2 4
Intraoperative (specify)*		-	<u> </u>	 -		- ' '	1		14	Note 2, 3, 4
Intraoperative Neurological				 						
Pediatric		N	N	N		N	N		N	Note 2 2 4
Small organ(specify)**		N	N	N	 	N	N		N	Note 2, 3, 4
Neonatal Cephalic	_	N	N	N	<u> </u>	N	N		N	Note 2, 3, 4 Note 2, 3, 4
Adult Cephalic	_	<u> </u>	 							, Note 2, 3, 4
Cardiac			<u> </u>	 						
Transesophageal	<u> </u>									
Transrectal							-			
Transvaginal			-	┌─						
Transurethral			_	<u> </u>						
Intravascular										 -
Peripheral Vascular		N	N	И		N	N		N	Note 2, 3, 4
Laparoscopic				<u> </u>						11010 2, 3, 4
Musculo-skeletal Conventional		N	N	N		N	N		N ·	Note 2, 3, 4
Musculo-skeletal Superficial		N	N	N		N	N		N	Note 2, 3, 4
Other (specify)***				1						11010 2, 5, 4
N=new indication; P=previously	clear	ed by	FDA;	E=ad	ded und	er Appendi	хE		<u> </u>	
Additional comments:Combined								ort B. Pos	ver + PW +R	
*Intraoperative include	des ab	domi	nal, th	огасіс	and vas	cular etc.		5,10		<u> </u>
**Small organ-breast										
***Other use include										
Note 1: Tissue Harme			g. The		re does	not use con	trast agents.			
Note 2: Smart3D								, .	·	
Note 3: iScape		•				,				
Note 4: iBeam		-		•			· · · · ·			
(PLEASE DO NO	OT W	RITE	BELC	W TI	IS LIN	E-CONTIN	IUE ON AN	OTHER PA	AGE IE NEE	DED)
							ice Evalua			

Prescription USE (Per 21 CFR 801.109)

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and Radiological Devices

510(k) Number <u>K083001</u>

System _				Haits	saucei						
Model:		7L1	`4s		;						
510(k) Number(s)							_				
	Mode of Operation										
Clinical Application	Α	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic				ļ							
Fetal											
Abdominal		N	N	N		N	N		N	Note 2, 3, 4	
Intraoperative (specify)*		Ν	N	N		N	N		N	Note 2, 3, 4	
Intraoperative Neurological											
Pediatric		N	N	N		N	N		N	Note 2, 3, 4	
Small organ(specify)**		N	N	N		N	N		N	Note 2, 3, 4	
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N		N	Note 2, 3, 4	
Transesophageal						1					
Transrectal								1			
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N		N	Note 2, 3, 4	
Laparoscopic		1									
Musculo-skeletal Conventional		N	N	N	j	N	` N		N	Note 2, 3, 4	
Musculo-skeletal Superficial		N	N	N		N	N		N	Note 2, 3, 4	
Other (specify)***											
N=new indication; P=previously	/ clear	ed by	FDA	; E=a	dded und	ier Append	ix E				
Additional comments:Combined	1 mod	es: B-	М, Р	W+B,	Color+	B, Power	+ B, PW +C	olor+ B, Po	wer + PW +1	3.	
*Intraoperative inclu	des al	odomi	nal, th	погасі	c, and va	ascular etc.					
**Small organ-breas	t, thy	oid, te	estes,	etc.							
***Other use include	es Urc	logy.									
Note 1: Tissue Harm	onic	magir	ıg. Th	e feat	ure does	not use co	ntrast agents	-			
Note 2: Smart3D											
Note 3: iScape											
Note 4: iBeam	-								•		
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510(k) Number_